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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,710	09/22/2003	Vincent Peter Bavaro	ACSC-63888 (4045P)	1413

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FULWIDER PATTON LEE & UTECHT, LLP
Gunther O. Hanke
Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045

EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1772	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,710	BAVARO ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112 rejections of claims 1 and 4-11 of record in the Office Action mailed March 6, 2007, Pages 2-3 Paragraph 3, have been withdrawn due to Applicant's amendments in the Paper filed May 3, 2007.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al (USPN 5,776,141) in view of Elliott (US 2003/0164063).

Regarding claims 1 and 4-5, Klein et al teach a radio marker for an intraluminal medical device comprising a polymer and radiopaque particles (col.11, l.15-30). The polymer is a polyether block amide copolymer and said radiopaque particles comprise tungsten powder, which is loaded approximately 36 volume percent of said marker since it is 90% by weight (col.11, l.22-26). The blend of the polymer and the radiopaque particles forms a highly radiopaque yet relatively flexible radiopaque marker configured for securing to the intraluminal medical device and the radiopaque particles (col.11, l.15-30) The marker is formed with a minority of the volume metal solids and the majority of volume nonmetal.

Klein et al fail to teach adding a wetting agent for facilitating encapsulation of said particle by said polymer and the diameter of the particles. However, Elliott teaches that to improve the packing density of tungsten powder the powder is milled to deagglomerate the fine particle clusters. To get higher packing densities such as 36 volume percent and

approximately 91.3 weight percent, Elliott teaches the mean particle size is between 1 and 10 microns (p.2, paragraph 43). Elliott further teaches specific examples wherein when the median particle diameter is about 10 microns, the 90% of the particles have a diameter less than 18.5 microns (p.6, paragraph 94). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that when the mean particle size is within the range of 1 and 10 microns the maximum diameter of substantially all particles would be about 20 microns. Furthermore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that when 90% of the particles have a diameter less than 18.5 microns very few if any of the particles have a diameter greater than 20 microns. Also, one of ordinary skill in the art would have expected absent any teaching to the contrary that a statistically insignificant amount of particles having a diameter greater than 20 microns would not render the article different, besides the fact that the claim specifies "about" 20 microns which would include some diameters greater than 20 microns.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiopaque particles of Klein et al with a mean

diameter of at least 2 microns and a maximum diameter of about 20 microns in order to maximize the packing density and ultimately be able to form a combination with 36 volume percent and approximately 91.3 weight percent radiopaque particles, as taught by Elliott.

Furthermore, Elliott teaches that a wetting agent such as maleic anhydride graft polyolefin is blended with the polymer forming the radiopaque particle containing article as a strength enhancing agent (p.5, paragraph 92). Therefore, it would have been obvious to one having ordinary skill in the art to add maleic anhydride graft polyolefin to a tungsten and polymer mixture in order to enhance the strength of the mixture, as taught by Elliott.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a maleic anhydride graft polyolefin to the radiopaque marker of Klein et al in order to enhance the strength of the mixture, as taught by Elliott. Because, the marker taught by the combined teaches of Klein et al and Elliott meet all of the structural limitations claimed there is a sound basis that the marker radiopacity is substantially similar to that of a 0.0125 inch thick Platinum/10% Iridium marker and the polymer forms a continuous binder encapsulating each radiopaque particle in the

same manner as the claimed invention since these would be latent properties of the article.

Regarding claims 6-8, the limitations that the particles are produced by a pusher process or by an atomization process are given little patentable weight in an article claim. Although all limitations are considered, process limitations in an article claim are only given weight insofar as the structural differences the process teaches. In this case, because the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94), the structural differences provided by the processes of forming particles that are substantially equiaxed are taught by Elliott.

Regarding claim 9, it is well known in the art that antioxidants are added to elastomers in order to prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation. Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the marker of Klein et al, since it is well known in the art as a

common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claim 10, Pebax is thermoplastic.

Regarding claim 11, Klein et al teach the marker has a ring shape with is a tubular structure.

Response to Arguments

5. Applicant's arguments filed May 3, 2007 have been fully considered but they are not persuasive.

In response to Applicant's argument that Elliot would statistically contain particles with a diameter greater than 20 microns when 90% have a diameter less than 18.5 microns, it is agreed that most likely there would be some particles with a diameter greater than 20 microns when only providing a 90% value and not an absolute maximum. First, Applicant's claim does not required that no tungsten particles have a diameter greater than 20 microns, it requires that the maximum diameter is about 20 microns, which would include some diameters greater than 20 microns. Furthermore, one of ordinary skill in the art would have recognized absent a showing to the contrary that an article having a statistically small amount of particles having a diameter greater than about 20 microns would be obviously the

same as an article having absolutely no particles having a diameter greater than about 20 microns.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489.

The examiner can normally be reached on Monday thru Friday from 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
June 30, 2007

ALICIA CHEVALIER
PRIMARY EXAMINER